

BONIVA(R) F. C. Tablets 150 mgVersion
2.1Revision Date:
11-16-2021Date of last issue: 03-03-2020
Date of first issue: 06-10-2017**SECTION 1. IDENTIFICATION**

Product name : BONIVA(R) F. C. Tablets 150 mg

Product code : RO200-5450/F07

Common name(s),
synonym(s) of the substance : BONVIVA Film Coated Tablets
BONIVA F.C. Tablets**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone : US Chemtrec phone (800)-424-9300
number**Recommended use of the chemical and restrictions on use**

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin corrosion : Category 1B

Serious eye damage : Category 1

Carcinogenicity : Category 2

Specific target organ toxicity : Category 2
- repeated exposure**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or

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repeated exposure.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ibandronate	138926-19-9	36.3
Lactose-1-Hydrate	64044-51-5	35.0
Cellulose	9004-34-6	12.9
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	4.8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	4.8
Octadecanoic acid	57-11-4	1.9
Titanium oxide (TiO ₂)	13463-67-7	1.8
Poly(oxy-1,2-ethanediyl), .alpha.-	25322-68-3	0.5

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hydro-.omega.-hydroxy- non hazardous compounds	Not Assigned	2.0
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SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Consult a physician.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye damage.
Suspected of causing cancer.
May cause damage to organs through prolonged or repeated exposure.
Causes severe burns.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
 Nitrogen oxides (NOx)
 Oxides of phosphorus
 Carbon monoxide
 Carbon oxides
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
 Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid exposure
 Use personal protective equipment.
 Avoid dust formation.
 Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.
 Prevent further leakage or spillage if safe to do so.
 If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
 Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.
 Do not breathe vapors/dust.
 Avoid exposure - obtain special instructions before use.
 Avoid contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated

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place.

Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Electrical installations / working materials must comply with the technological safety standards.

- Storage temperature : Protected from heat and light
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, Polyethylene bag in metal drum, glass, Blister packages

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ibandronate	138926-19-9	IOEL	0.002 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total	10 mg/m ³	OSHA P0

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		dust)		
		TWA	10 mg/m3 (Titanium dioxide)	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Ibandronate	Surface waters	0.39 µg/l
	Remarks: Based on acute data	

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
 Effective dust mask

Hand protection

In case of contact through splashing:
 Material : Nitrile rubber
 Break through time : > 30 min
 Glove thickness : > 0.11 mm

In case of full contact:
 Material : butyl-rubber
 Break through time : > 480 min
 Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.
 Replace torn or punctured gloves promptly.
 Eye protection : Eye wash bottle with pure water
 Tightly fitting safety goggles
 Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Dust impervious protective suit
 Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees mandatory

Hygiene measures : When using do not eat or drink.
 When using do not smoke.
 Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : white, off-white

SAFETY DATA SHEET

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Odor	:	Not applicable
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous	:	No decomposition if stored and applied as directed.

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reactions

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: 2,142 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 45.42 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method**Components:****Ibandronate:**

Acute oral toxicity : LD50 Oral (Rat): 811 mg/kg

Lactose-1-Hydrate:

Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

Octadecanoic acid:Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat): > 5,000 mg/kg

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Method: OECD Test Guideline 425Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Causes severe burns.

Product:

Remarks : Extremely corrosive and destructive to tissue.

Components:**Ibandronate:**Result : Causes burns.
Remarks : Extremely corrosive and destructive to tissue.**Octadecanoic acid:**Species : Rabbit
Exposure time : 24 h
Method : Patch Test 24 Hrs.
Result : No skin irritation**Titanium oxide (TiO₂):**Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation**Serious eye damage/eye irritation**

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:**Ibandronate:**

Remarks : May cause irreversible eye damage.

Octadecanoic acid:Species : Rabbit
Result : No eye irritation**Titanium oxide (TiO₂):**

Species : Rabbit

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Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Ibandronate:**Species : Guinea pig
Result : Did not cause sensitization on laboratory animals.**Titanium oxide (TiO₂):**Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406**Germ cell mutagenicity**

Not classified based on available information.

Components:**Ibandronate:**Genotoxicity in vitro : Test Type: in vitro test
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Species: laboratory animal
Result: negative**Carcinogenicity**

Suspected of causing cancer.

Components:**Ibandronate:**Species : laboratory animal
Result : negative**Lactose-1-Hydrate:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Cellulose:

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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Octadecanoic acid:

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Ibandronate:

Effects on fertility : Species: laboratory animal
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Species: laboratory animal
Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure

Not classified based on available information.

Components:

Lactose-1-Hydrate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ibandronate:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Lactose-1-Hydrate:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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Species : laboratory animal
NOAEL : 0,15 mg/kg/w
Application Route : i.v.
Exposure time : 26 Weeks
Symptoms : kidney toxicity
Remarks : Chronic toxicity

Aspiration toxicity

Not classified based on available information.

Components:**Ibandronate:**

No data available

Lactose-1-Hydrate:

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Ibandronate:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 200 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes

LC0 (Cyprinus carpio (Carp)): 86 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 180 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes

NOEC (Daphnia magna (Water flea)): 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 0.390 mg/l
Exposure time: 72 h

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Method: OECD Test Guideline 201

GLP: no

Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.218 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: no

Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: no

Remarks: nominal concentration

ErC50 (Selenastrum capricornutum (green algae)): 4.7 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

EyC50 (Selenastrum capricornutum (green algae)): 1.4 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

NOEC (Selenastrum capricornutum (green algae)): 0.22 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: yes

Toxicity to microorganisms : (activated sludge): 41.5 mg/l
 Exposure time: 28 d
 Test Type: aerobic
 Method: OECD Test Guideline 301B
 GLP: yes
 Remarks: no adverse influence on substrate biodegradation

NOEC (activated sludge): 1,300 mg/l

Exposure time: 5 h

Test Type: Growth inhibition

GLP: no

Remarks: Barely inhibitory on aerobic bacterial reproduction (activated sludge)

Lactose-1-Hydrate:

Toxicity to fish : LC50: > 100 mg/l
 Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

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- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Cellulose:**Ecotoxicology Assessment**

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Titanium oxide (TiO₂):

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test
- LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
- EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253
- NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

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Biodegradability : Concentration: 41.5 mg/l
Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

Concentration: 1,000 mg/l
Result: Not inherently biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

Octadecanoic acid:

Biodegradability : Biodegradation: 44 %

Titanium oxide (TiO₂):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Ibandronate:**Partition coefficient: n-
octanol/water : Remarks: No data available**Lactose-1-Hydrate:**Partition coefficient: n-
octanol/water : log Pow: -5.03**Cellulose:**Partition coefficient: n-
octanol/water : Remarks: No data available**Stearic acid:**Partition coefficient: n-
octanol/water : log Pow: 8.23**Titanium dioxide:**Partition coefficient: n-
octanol/water : Remarks: No data available

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Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Very toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste
handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3261
Proper shipping name : CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : 8

IATA-DGR

UN/ID No. : UN 3261
Proper shipping name : Corrosive solid, acidic, organic, n.o.s.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : Corrosive
Packing instruction (cargo
aircraft) : 864

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Packing instruction : 860
(passenger aircraft)
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3261
Proper shipping name : CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : 8
EmS Code : F-A, S-B
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3261
Proper shipping name : Corrosive solid, acidic, organic, n.o.s.
(Ibandronate mixture)
Class : 8
Packing group : III
Labels : CORROSIVE
ERG Code : 154
Marine pollutant : no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Carcinogenicity
Specific target organ toxicity (single or repeated exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCOMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know**

Cellulose	9004-34-6
Titanium oxide (TiO ₂)	13463-67-7

Pennsylvania Right To Know

Ibandronate	138926-19-9
Lactose-1-Hydrate	64044-51-5
Cellulose	9004-34-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
Titanium oxide (TiO ₂)	13463-67-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Titanium oxide (TiO ₂)	13463-67-7

The ingredients of this product are reported in the following inventories:

AICC : Not in compliance with the inventory

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DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Ibandronate

non hazardous compounds

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

SAFETY DATA SHEET

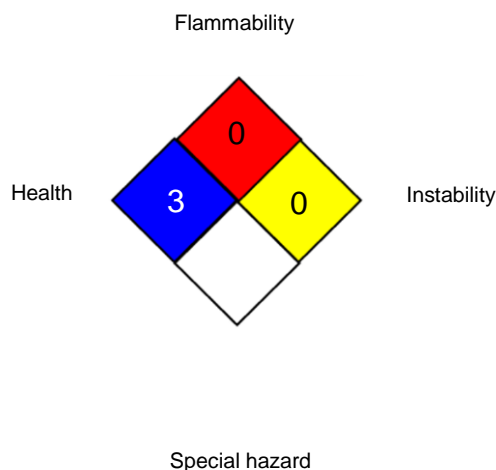
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NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology

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Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 11-16-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2010